

*Timcaps (dextro-amphetamine sulfate capsules)*. 502(a)—while held for sale, the labeling accompanying the article, namely, the labels to be used in repacking the article, contained a false and misleading statement which represented and suggested that the Donaker Drug Company, Des Moines, Iowa, was the manufacturer of the article.

*#1 capsules and #2 capsules*. 502(b)—while held for sale, the articles failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents; 502(d)—the articles contained amobarbital, a derivative of barbituric acid, and their labels failed to bear the name and quantity or proportion of such derivative; 502(e) (2)—the labels of the articles failed to bear the common or usual name of each active ingredient; 502(f) (1)—their labeling failed to bear adequate directions for use; and 503(b) (4)—the articles were subject to 503(b) (1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

**DISPOSITION:** Spartan-Rex Chemical Co. appeared as claimant for the articles of *Triple-sulfa No. 1 tablets*, *Quinidine Sulfate capsules* (7 btl.), *sulfadiazine tablets*, *methyltestosterone sublingual tablets*, *Timcaps (dextro-amphetamine sulfate capsules, 15 mgs.)* (22 btl.); and having consented to the entry of a decree, judgment of condemnation was entered on 2-6-59 against all of the articles under seizure and the court ordered that the articles claimed by Spartan-Rex Chemical Co. be released under bond for relabeling, and that the remainder of the articles under seizure be delivered to a State hospital.

#### DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS\*

**5708. Aspirin tablets.** (F.D.C. No. 41700. S. No. 34-029 P.)

**QUANTITY:** 42 boxes, each containing 12 ctns. of 12 tins each, at Lehighton, Pa.  
**SHIPPED:** 6-28-48, from Memphis, Tenn.

**RESULTS OF INVESTIGATION:** Examination showed the article to be 5 grain *aspirin tablets* containing 0.55 percent free salicylic acid, whereas, the United States Pharmacopeia permits a maximum of 0.15 percent free salicylic acid per aspirin tablet.

**LBELED:** 5-8-58, M. Dist. Pa.

**CHARGE:** 501(b)—the quality and purity of the article, while held for sale, fell below the standard for *aspirin tablets* set forth in the United States Pharmacopeia since the article contained more than the permitted amount of free salicylic acid; 502(f) (1)—the labeling of the article failed to bear adequate directions for use; and 502(f) (2)—the labeling of the article failed to bear adequate warnings against misuse by children, in that, in lieu of a dosage statement for children under 3 years of age, it did not bear a statement that for the 3 year and under age group a physician should be consulted for dosage, and its label did not bear a statement warning that the product should be kept out of reach of children.

**DISPOSITION:** 6-13-58. Default—destruction.

\*See also Nos. 5705, 5707.